K090938

Odyssey Medical, Inc.
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JUN - 4 2009

510K Summary

Submitted: 03/12/2009
By: Terry Green
Registration Number: 1060840
Trade Name: Punctal Occluder
Common Name: Plug, Punctum
Product Name: Micro Flow
Classification Name: LZU
Classification Panel: Ophthalmic
Device Class: Unclassified
Performance Standards: None Established

Summary:

This device, made of medical grade silicone, titanium dioxide as a colorant and utilizing a proprietary surface treatment made under current good manufacturing practices, is a small, generally "plug" shaped design. Punctal Occluders are intended for the treatment of "dry eye" conditions through partial occlusion of individual punctual openings. By material, design and intended use, Micro Flow is substantially equivalent to the previous Odyssey Punctal Occluder (K970631).

Differences between the two devices may be described as follows:

The original Odyssey plug under 510 K970631 has a larger angle nose, no through hole and shorter in length.

The new design "Micro-Flow" is similar to the original plug with the exceptions of the following:

- A through hole which allows for partial occlusion of individual punctual openings.
- A .002 ridge on nose to help support the designed through hole.
- Angle on nose (tip) is smaller.

Alternative methods of punctual occlusion are either permanent or difficult to reverse. In contrast, the submitted method is both functionally safe and fully reversible. Unlike some other methods, this device does not require the breach of intact tissue surfaces or the risk of damaging said surface should reversal become desirable.

Kim Finch for Terry Green — Kim Finch
(Signature) (Typed Name)

6/2/09 — K090938
(Date) (Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Oddyssey Medical, Inc.
c/o Terry R. Green
2975 Brother Blvd.
Bartlett, Tennessee 38133

JUN - 4 2009

Re: K090938
Trade/Device Name: Micro Flow Punctal Occluder
Regulatory Class: Unclassified
Product Code: LZU
Dated: March 26, 2009
Received: April 3, 2009

Dear Mr. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K090938

Device Name: Micro Flow

Indications for Use:

Punctal Occluders (plugs) are indicated for the treatment of "dry eye" syndrome.

Prescription Use X_ Over-The-Counter Use

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090938